

APPLICANT(S): STEINER, Mitchell S. et al.  
SERIAL NO.: 10/747,691  
FILED: December 30, 2003  
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## REMARKS

### Status of Claims

Claims 1-40 are pending in the application. Claims 11-40 have been withdrawn from consideration. Claims 1-10 have been rejected. Claims 1 and 7-10 have been amended.

Claims 2-4 have been canceled without prejudice or disclaimer. In making this cancellation without prejudice, Applicants reserve all rights in these claims to file divisional and/or continuation patent applications.

Claims 5-6 have been amended in response to Notice of Non-Compliant Amendment (37 CFR 1.121), dated October 18, 2007.

### Double Patenting Rejections

In the Office Action, the Examiner rejected claims 1-10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/778,333. Applicants request that this rejection be held in abeyance with respect to the reference application until allowable claims are obtained in the referenced Application.

## CLAIM REJECTIONS

### 35 U.S.C. § 112 Rejections

Claims 1-4 were rejected by the Examiner under 35 U.S.C. § 112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is directed to "a method of treating a subject with hot flashes, said method comprising the step of administering to said subject an anti-estrogen agent and/or its pharmaceutically acceptable salt, hydrate, N-oxide, or any combination thereof, wherein said anti-estrogen is Toremifene." Claims 2-4 have been cancelled, making rejection of these claims moot.

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### 35 U.S.C. § 102 Rejections

Claims 1 and 5-10 were rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by WO 01/49673 A2 (Bhagwat *et al.*). Bhagwat *et al.* describe different compounds, which are not Toremifene, to treat a different clinical condition. It would not be obvious to one skilled in the art that significantly different compounds, described for use in different clinical indications, would be comparable.

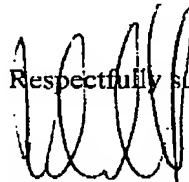
Claims 1 and 2 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Merchenthaler *et al.* ("The effect of estrogens and antiestrogen in a rat model for hot flush", *Maturitas* 1998, 3:307-316). Applicants disagree. Merchenthaler *et al.* do not describe use of toremifene to treat hot flashes.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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Dated: 18 November 2007  
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